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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/706,108	11/12/2003	Galla Chandra Rao	IMMC 234.1 (CIP)	6497

40541 7590 09/25/2006

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EXAMINER	
CANELLA, KAREN A	
ART UNIT	**PAPER NUMBER**
1643	

DATE MAILED: 09/25/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/706,108	RAO ET AL.	
	Examiner	Art Unit	
	Karen A. Canella	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) 1-22 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) 1-22 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-22 are pending and examined on the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-22 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an improvement which is using different control cells with different intensities of the same fluorescent marker or with different fluorescent markers to spike patient samples to provide an indication of the efficacy of recovery of an actual tumor cell or rare cell, does not reasonably provide enablement for an improvement which is using two or more populations of control cells having different fluorescent markers at the same intensity to spike a patient sample at the same concentration. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The factors considered when determining if the disclosure satisfies the enablement requirement and whether any necessary experimentation is undue include, but are not limited to: 1) nature of the invention, 2) state of the prior art, 3) relative skill of those in the art, 4) level of predictability in the art, 5) existence of working examples, 6) breadth of claims, 7) amount of direction or guidance by the inventor, and 8) quantity of experimentation needed to make or use the invention. In re wands, 858 F.2d 731, 737.8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

Claims 1-22 require an improvement wherein two fluorescently distinct sets of stabilized cell populations are added to the instant method or kit. Claims 5 and 17 specify that the cell populations are external control cells.

(A) addition of two fluorescently distinct control cell populations in an external control as an improvement over the art

With regard to the improvement encompassing the use of the control cells as external controls, it is noted that the art teaches that the external control assay allows one to determine the recovery of spiked tumor cells which should fall within set specification and that such a use of the control cells is not ideal because it does not control for random errors that would influence the actual sample and that the best control is the internal control (page 21, line 17 to page 22, line 2). The specification provides no teachings as to how the presence of two fluorescently distinct control cell populations would constitute an improvement over the prior art when used as an external control. One of skill in the art would reasonable conclude that information obtained from using fluorescently distinct control cell population as an external control would not be improved upon by the addition of a second fluorescently distinct control cell population. One of skill in the art would be subject to undue experimentation in order to practice the claimed invention as an improvement over the prior art using two fluorescently distinct control cell populations.

(B) addition of two fluorescently distinct control cell populations as an internal control for an improvement over the art

When given the broadest reasonable interpretation, two fluorescently distinct sets of stabilized cell populations includes fluorescently distinct populations which are of the same fluorescent intensity as well as use of the two fluorescently distinct cell populations at the same concentration in a patient sample. The specification teaches (page 23, lines 22-27) that if the density of the target cell is suspected to be outside the predetermined antigen density, and the aggregation technique described in U.S. 6,523,982 is not available, the problem can be circumvented with the use of two separate populations of control cells, one set having a low antigen density and another having a high antigen density. The specification teaches in Example 10 (page 42) that using one population of control cells at one cell concentration can validate the test, but would not provide for a measure of the efficiency of cellular recovery at different cell concentrations. The specification teaches that the number of tumor cells in a patient sample may not be the same as the number of tumor cells used as the internal control. The specification points out that the recovery of spiked tumor cells in linear from 1 cell/ml to 5000 cell/ml, but what is not know is how the recovery of control cells from a patient sample behave at various concentrations, but that this can be assessed by spiking control cells at various concentrations

into the patient sample. The specification points out (continuing in Example 10, page 42) that this cannot be done by using control cell populations with the same fluorescent intensity at different concentrations but can be achieved by using different control cells with different intensities of the same fluorescent marker or with different fluorescent markers. The specification does not teach any improvement associated with the inclusion of control cell populations with the same fluorescent intensity, or the inclusion of distinct control cells at the same concentration in the patients sample.

The scope of enablement in the claims must be commensurate with the scope of enablement set forth in the specification, and without further teachings or guidance from the specification, one of skill in the art would be subject to undue experimentation in order to ascertain an improvement associated with the inclusion of control cell populations having distinct fluorescent markers but at the same intensity, or control cell populations used at the same concentration in a patient sample.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned

with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-22 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 35-59 of copending Application No. 09/801,471. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are obvious over the reference claims. The claims in the '471 application encompass a single type of control cell which is labeled with at least two fluorescent labels having different emission spectra. The instant claims require two or more fluorescently distinct sets of stabilized cell populations. It would have been obvious to one of skill in the art that the individual sets of control cells used in the '471 application, such as those in claims 56-59, can be combined for use as controls with an unknown blood sample from a patient not yet diagnosed as having cancer. One of skill in the art would already have the appropriate control in the sample in the event that rare circulating cancer cells were present in said sample.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen A. Canella whose telephone number is (571)272-0828. The examiner can normally be reached on 10-6:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on (571)272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Karen A. Canella, Ph.D.
9/18/2006

KAREN A. CANELLA PH.D
PRIMARY EXAMINER